DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 1, 2016

B. Braun Avitum AG
% Tracy Maddock, RAC
Sr. Regulatory Affairs Specialist
B. Braun Medical, Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341

Re: K143482
Trade/Device Name: Xevonta Dialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: February 26, 2016
Received: February 29, 2016

Dear Tracy Maddock,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143482

Device Name
xevonta dialyzer

Indications for Use *(Describe)*
The xevonta dialyzer is designed for single use in acute and chronic hemodialysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510(k) SUMMARY K143482

APPLICANT:

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DATE: February 29, 2016

DEVICE NAME:

xevonta dialyzer
Models: xevonta 1.2 m^2, xevonta 1.5 m^2, xevonta 1.8 m^2, xevonta 2.0 m^2, xevonta 2.3 m^2

COMMON OR USUAL NAME:

High permeability polysulfone high flux dialyzer

DEVICE CLASSIFICATION:

Class II
21 CFR §876.5860, High permeability hemodialysis system
Product Code: KDI

PREDICATE DEVICES:

Diacap HiFlo 23 Dialyzer, B. Braun Avitum AG, K100334, Class II, KDI, 876.5860

Diacap HIPS Dialyzers, B. Braun Avitum AG, K071518, Class II, KDI, 876.5860

DESCRIPTION:

The xevonta dialyzer is a polysulfone high flux dialyzer with the surface areas 1.2 m^2, 1.5 m^2, 1.8 m^2, 2.0 m^2, 2.3 m^2. It is designed for single use in acute and chronic

hemodialysis. The dialyzer is gamma sterilized, with a non pyrogenic fluid path, and does not contain natural rubber latex.

The polysulfone hollow fiber (membrane) is housed within a plastic cylinder containing four ports: two ports for blood compartment access and two ports for dialysate access.

INTENDED USE:

The xevonta dialyzer is designed for single use in acute and chronic hemodialysis.

COMPARISON FOR SUBSTANTIAL EQUIVALENCE:

Two predicate devices, i.e. B. Braun Avitum AG's Diacap HiFlo 23 Dialyzer (K100334) and Diacap HIPS dialyzer (K071518) were used for comparison with the new device.

The new device has the same indications for use as the marketed predicate devices, i.e. for single use in acute and chronic hemodialysis.

Membrane/ housing materials and surface areas of the new device correspond to those of the predicate devices.

Modified technological characteristics of the new device are changes to membrane design, change of cap colorant in addition to alternative suppliers (potting resin, PVP).

Briefly, modified design characteristics of the membrane include changes in the number of membrane fibers and length of the fiber bundle, the inner fiber diameter, the wall thickness of the membrane and the number of pores.

These modified characteristics of the membrane are achieved by a validated manufacturing process of the membrane.

SAFETY AND EFFECTIVENESS:

To assess the effects of the modified characteristics of the new device and to demonstrate equivalence with the predicate devices, the following data assessed by scientific methods, performance and clinical data are provided:

Biocompatibility testing:

Testing was performed according to ISO 10993-1 and FDA Guidance "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for an externally communicating device contacting circulating blood for prolonged contact (category B).

In vitro performance testing:

- ultrafiltration rate
- pressure drop blood side and dialysate side

- clearances of urea, creatinine and vitamin B_{12}
- mechanical hemolysis

Clinical testing:

- comparison of in-vitro and in-vivo ultrafiltration coefficient

Results of the testing demonstrate that the proposed device performs similarly to the predicate device and can be used safely and effectively according to its intended use.

CONCLUSION:

The data provided for the new device demonstrates that xevonta dialyzers are as safe and effective as the marketed predicate devices. The differences, between subject device and predicate devices, do not raise any new issues of safety and effectiveness. The xevonta dialyzers, therefore, are substantially equivalent to the predicate devices.